UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	
THIS DOCUMENT RELATES TO: *The City of New York v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Albany v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00425) *County of Allegany v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06231) *County of Broome v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00456) *County of Cattaraugus v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06242) *County of Cayuga v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00423) *County of Chautauqua v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06204) *County of Chemung v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06744) *County of Chenango v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00354) *County of Columbia v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00867) *County of Cortland v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00881) *County of Dutchess v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 05-CV-06458) *County of Essex County v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00878) *County of Fulton v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00519)	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 03-10643-PBS Judge Patti B. Saris **DEFENDANT SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE'S ("GSK's") MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT IN THE NEW YORK COUNTY CASES**

County of Genesee v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06206) *County of Greene v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00474) *County of Herkimer v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00415) *County of Jefferson v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00715) *County of Lewis v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00839) *County of Madison v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00714) *County of Monroe v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06148) *County of Nassau v. Abbott Laboratories, Inc., et al.* (E.D.N.Y. No. 04-CV-5126) *County of Niagara v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06296) *County of Oneida v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00489) *County of Onondaga v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00088) *County of Ontario v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06373) *County of Orange v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 07-CV-2777) *County of Orleans v. Abbott Laboratories, Inc., et al.* (W.D.N.Y. No. 05-CV-06371) *County of Putnam v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Rensselaer v. Abbott Laboratories, Inc., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Rockland v. Abbott Laboratories, Inc., et al.* (S.D.N.Y. No. 03-CV-7055)	

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Introduction

SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), moves for summary judgment with respect to all GSK NDCs at issue that meet the "WAC List Price" liability test this Court articulated and applied in its June 2007 decision following the Track One trial. *See In Re Pharmaceutical Industry Average Wholesale Price Litigation,* 491 F. Supp. 2d 20, 104-06 (D. Mass. 2007). Under that test, there can be no liability if more than 50% of a drug's sales each year were made at transaction prices that were within 5% of the manufacturer's reported Wholesale Acquisition Cost ("WAC") for that drug. *Id.* This test (referred-to herein as the "WAC List Price" test) should also apply to the claims of the New York Counties asserted against GSK for the fundamental reason that conduct that was held, as a matter of law, not to be deceptive under the Massachusetts statute at issue in the Track One trial cannot be deceptive under the materially identical New York Deceptive Acts and Practices Statute either. As demonstrated below, 208 of the 262 GSK NDCs at issue pass the WAC List Price test, and those that remain are low-volume drugs. Application of this test will therefore drastically reduce the scope of the case against GSK.

There is no reason to delay the entry of judgment on these GSK NDCs. Despite the limited stay of discovery here for drugs with alleged AWP "spreads" of 30% or less, GSK has already provided the New York Counties with extensive discovery relating to virtually all of its Medicaid-covered drugs (regardless of their alleged AWP "spreads"), including a comprehensive set of GSK's sales transaction data for the 1997-2005 period and virtually all of the documents, data and depositions taken in the multiple WAC/AWP cases filed against GSK over the last half dozen years (including in the MDL and in a prior WAC/AWP case filed against GSK by the State of New York). This undisputed

evidence clearly shows that GSK's reported WACs for the NDCs subject to this motion were legitimate list prices that pass the WAC List Price test previously articulated by this Court.

For each of the 208 GSK NDCs that pass the WAC List Price test (which are set forth in Table B.1 of the Affidavit of Dr. Eric Gaier appended hereto and are also listed in Exhibit A to the proposed Order accompanying this Motion), GSK now seeks summary judgment based on the application of that test alone. In addition, GSK also seeks summary judgment as to the Counties' claims relating to two additional GSK NDCs -- Zofran 2mg/ml vials (NDC 00173044200) and Amoxil 500 mg capsules (NDC 00029600732) -- on the separate ground that they were explicitly released as part of a 2006 settlement agreement between GSK and the State of New York.

I. Statement of Undisputed Material Facts

A. GSK's List Price Reporting

GSK and its predecessors have, for the entire 1997-2005 period now at issue in this case, reported a "Wholesale Acquisition Cost" ("WAC"), or a WAC equivalent, to First DataBank and the other commercial price reporting services.[1] Since shortly after the merger that formed GSK in 2001, GSK has reported a WAC, and only a WAC (*i.e.*, no AWP or anything like it), for all of its prescription pharmaceuticals. *See* Statement of Undisputed Material Facts in Support of GSK's Motion for Partial Summary Judgment in the New York County Cases at ¶ 1a (hereinafter "GSK's Statement of Facts" or "GSK's SOF"); Affidavit of David A. Moules dated February 25, 2004 at ¶ 5 (hereinafter

[1] The Court found in CMO No. 33, ¶ 7 (dated September 14, 2007) that "AWP-based claims that accrued prior to 1998 face a substantial statute of limitations defense," and the Court has limited the discovery that has proceeded in this case since then to the period 1997-2005.

"Moules 2004 Aff."),[2] appended as Exhibit 3 to GSK's Statement of Facts.[3] Since its formation, GSK has specifically defined its reported "WAC" in its routine pricing communications to First Databank and its customers as "the listed price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates, or chargebacks." GSK SOF at 1a; *see* GSK price reporting letters (Ex. 5).

Prior to the merger that formed GSK in early 2001, GSK predecessor Glaxo Wellcome, Inc. ("GW") reported a WAC-equivalent that it called "NWP" ("Net Wholesale Price"). GSK's SOF at ¶ 1b; Affidavit of GSK Vice President David A. Moules dated September 25, 2006, at ¶ 4 (hereinafter "Moules 2006 Aff.") (Ex. 6). GW included the following definition of this WAC-equivalent in its routine pricing communications, starting in 1999: "List price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates or chargebacks." GSK's SOF at ¶ 1b; *See* GW price reporting letters (Ex. 7).[4]

Prior to the 2001 merger, GSK's other predecessor -- SmithKline Beecham Corporation ("SB") -- reported a WAC-equivalent that it called "WPP" ("Wholesaler Purchase Price"). GSK's SOF at ¶ 1c; Moules 2006 Aff. at ¶ 5 (Ex. 6). SB defined this WAC-equivalent in its routine pricing communications, starting in 2000, as follows: "SB's price to SB's wholesaler class of trade, without taking into account prompt pay

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2 Mr. Moules has served as GSK's Rule 30(b)(6) deponent on price reporting issues, and his May 8, 2007 deposition in the Alabama AWP case was cross-noticed in this case by Stipulation. *See* Stipulation dated April 18, 2007 at ¶ 6, appended as Ex. 4 to GSK's SOF; *see also* Affidavit of Frederick G. Herold, Esq. (hereinafter "Herold Aff.") at ¶¶ 2-3, appended as Ex. 1 to GSK's SOF.

3 All references hereinafter to exhibits will be abbreviated as "Ex." and refer to exhibits appended to GSK's SOF.

4 In addition, in a proposed Medicaid pricing contract submitted by GSK predecessor Glaxo, Inc. to the New York Medicaid Program as early as 1990, Glaxo explicitly defined its reported "Net Wholesale Price" as "the wholesale list price." GSK's SOF at ¶1b ; *See* Market Adjustment Agreement at 2 (Ex. 9).

discounts or other pricing or promotional concessions paid to wholesalers, or chargebacks paid to wholesalers on account of purchases by wholesalers' end user customers." GSK's SOF at ¶ 1c; *see* SB price reporting letters (Ex. 8).[5]

These GSK-specific definitions of WAC (and WAC equivalents)[6] were widely shared outside of the company, including with First DataBank. GSK's SOF ¶ 2; *See* Collection of GSK price reporting letters produced from First DataBank's files (Exs. 5, 7 and 8). They are entirely consistent with the definition of WAC as a "list price" that does not include discounts, which was set forth in numerous publications (including OIG reports and other government publications provided to state Medicaid agencies) as early as 1997.[7] They are also consistent with the statutory definition of WAC that was enacted into the federal Medicare and Medicaid statutes in December 2003. That statute defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or

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[5] Before SB became GSK in 2001 it also reported a "Suggested List Price" ("SLP"), which it defined as the "non-binding suggested resale price to end user purchasers who do not purchase under special contractual arrangements. Actual end user acquisition costs may be lower than the Suggested List Price, depending on wholesaler mark-ups, chargebacks or other pricing concessions." GSK's SOF at ¶ 1c; *See* SB price reporting letters (Ex. 8). The amount of the SLP was typically 1.25 times the WPP. GSK's SOF at ¶ 1c; Moules 2006 Aff. at ¶ 5 (Ex. 6).

[6] For ease of reference, we sometimes use "WAC" in this Memorandum to refer to both WAC and WAC equivalents such as NWP and WPP. We also sometimes use "GSK" to refer to both GSK and its predecessor companies.

[7] GSK's SOF at ¶ 3; *See, e.g., HHS OIG Report: Cost Containment of Medicaid HIV/AIDs Drug Expenditures, OEI-05-99-00611* at 5-7 (2001) (states that "for brand name drugs, manufacturers set the wholesale acquisition price as a list price for wholesalers to purchase drugs from manufacturers. … Both the WAC and the AWP operate as suggested list prices and are typically not what is paid. Buyers negotiate lower prices through the inclusion of discounts, rebates or free goods" (pp. 5-6); also contains a chart referring to WAC as a "list price" and AMP as the corresponding actual selling price for Medicaid (p. 7)) (relevant portions appended as Ex. 10); *GAO Report: Medicare – Payments for Covered Outpatient Drugs Exceed Providers' Cost,* at 23 (2001) (states that "WAC is the list price a wholesaler pays to a manufacturer, but it does not include discounts that may affect the net price") (relevant portions appended as Ex. 11);. E.M. (Mick) Kolassa, *Elements of Pharmaceutical Pricing* at 33 (1997) (states that "Wholesale Acquisition Cost (WAC) … is used by some publishers of pricing data to denote the ex-factory charge, before discounts, to the wholesaler") (relevant portions appended as Ex. 12).

reductions in price . . .." 42 U.S.C. § 1395w-3a (c) (6) (B) (Medicare Modernization Act); *see* 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(II) (incorporation of the MMA WAC definition into the Medicaid rebate statute); *see* GSK's SOF at ¶ 4.

To determine an AWP for GSK's and GSK predecessors' drugs during the 1997-2005 period, the price reporting services have chosen and applied a standard mark-up to the company's reported WAC list price. The mark-up has been either 1.20 or 1.25 depending on the particular drug, the time period and the reporting service. GSK's SOF at ¶ 5; Moules 2006 Aff. at ¶¶ 4-7 (Ex. 6).[8] From 1997 until after GSK was formed, the pricing publications typically published an AWP for GW products that was 1.20 times the WAC-equivalent that GW reported. GSK's SOF at ¶ 5; Moules 2006 Aff. at ¶ 4 (Ex. 6). During that same period, the pricing publications typically published an AWP for SB products that was 1.25 times the WAC-equivalent that SB reported. GSK's SOF at ¶ 5; Moules 2006 Aff. at ¶ 5 (Ex. 6). Since 2002, the AWPs that have been published for GSK products have differed between the major commercial price reporting publications. Since 2002 the Redbook, for example, has generally published an AWP for GSK products that is 1.20 times GSK's reported WAC, whereas First DataBank has generally published an AWP for GSK products that is 1.25 times GSK's reported WAC. These differing decisions concerning what AWPs to publish for GSK products, and what ratio should be applied to the WACs reported by GSK in order to derive those AWPs, were made by the price reporting services, not by GSK. GSK's SOF at ¶ 5; Moules 2006 Aff. at ¶ 7 (Ex. 6); Moules 2004 Aff. at ¶¶ 5-11 (Ex. 3).

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[8] The New York County plaintiffs allege in paragraph 12 and Exhibit F of the Revised First Amended Consolidated Complaint that the pricing services sometimes applied a higher WAC to AWP mark-up than the standard one for some drugs, but Exhibit F contains only one such allegation relating to GSK, from 1994.

B. Litigation and Settlement of Prior Pharmaceutical Pricing Litigation Filed Against GSK by the State of New York

In February 2003, the State of New York filed a pharmaceutical pricing complaint against GSK that made the same general allegations concerning the pharmaceutical list prices GSK reported as those now being asserted in this case by the New York Counties. GSK's SOF at ¶ 6; *See* Complaint in *The People of the State of New York, by Eliot Spitzer, Attorney General of the State of New York, v. GlaxoSmithKline, plc. et. al.*, Index No. 905-03 (Sup. Ct. N.Y., February 13, 2003) ("Complaint" in the "State of New York Case") (Ex. 13).[9] The Complaint in the State of New York case correctly alleged that GSK and its predecessors reported WACs and WAC-equivalents to the national drug pricing services, and that those services applied a "standard markup" to GSK's reported prices to determine the AWPs for GSK's products. GSK's SOF at ¶ 7; Complaint at ¶¶ 15, 17 (Ex. 13). The State further alleged that GSK's WACs for products covered by the New York Medicaid Program (as well as those covered by Medicare Part B) were fraudulently inflated -- resulting in inflated AWPs which were in turn used by the New York Medicaid Program to reimburse for GSK's drugs. GSK's SOF at ¶ 8; Complaint at ¶¶ 22, 28-29 (Ex. 13). Like the county plaintiffs here, the State of New York alleged, among other claims, that GSK violated New York's Deceptive Acts and Practices statute (N.Y. General Business Law § 349) and the New York statute prohibiting false statements to obtain public funds, N.Y. Social Services Law § 145-b. GSK's SOF at 8; Complaint at ¶ 3 and at First and Fifth Causes of Action (Ex. 13).

[9] This distinguishes GSK from all of the other defendants in the New York County cases except for Aventis and Pharmacia, which were the only other manufacturers also sued (to date) by the New York Attorney General's office.

The State of New York's case against GSK was vigorously litigated for more than three years. During that litigation, GSK provided the State with detailed GSK sales transaction data for a large number of GSK drugs and NDCs (both self-administered and physician-administered) covered by the New York Medicaid program. GSK's SOF at ¶ 9; *See* 3/28/05 GSK discovery letter (Ex. 14) and Herold Aff. at ¶ 13 (Ex. 1). After extensive analysis of the actual transaction prices at which GSK sold its drugs, including analysis of the discounts, rebates and chargebacks contained within GSK's data systems, the State of New York and GSK reached a settlement agreement that resolved the case in its entirety. The agreement was filed with the Supreme Court of the State of New York (County of Albany) as a Consent Order and Judgment on August 14, 2006. GSK's SOF at ¶ 10; *See* Consent Order and Judgment (Ex. 15) and Herold Aff. at ¶ 14 (Ex. 1).

GSK's settlement with the State of New York included approximately $2 million in Medicaid-related payments for certain NDCs of just three GSK drugs -- Kytril and Zofran injectibles (both physician-administered drugs that were subject to a prior settlement with the Department of Justice) and Amoxil (an off-patent multi-source drug). GSK's SOF at ¶ 11; Consent Order and Judgment at Section II 3(a), Section III. 1 and Attachment 2 (Ex. 15). Due to unique circumstances, these drugs were historically sold by GSK at significantly discounted prices. In exchange for GSK's settlement payments, the State of New York dismissed all claims related to Kytril and Zofran injectibles and certain Amoxil NDCs *with prejudice*, and provided a release that explicitly covered claims for those drugs by "New York or any of its counties." GSK's SOF at ¶ 11; Consent Order and Judgment at Section III. 6(a) and (8) and Attachment 2 (Ex. 15). In addition, after a comprehensive evaluation of GSK's pricing practices and the asserted claims with respect to all *other* GSK drugs reimbursed by New York Medicaid (referred-

to in the settlement agreement as "Medicaid Other Drug Claims"), the State of New York dismissed its claims for all of these "other drugs" without receiving any settlement payments relating to them -- but this dismissal was "without prejudice." GSK's SOF at ¶ 12; Consent Order and Judgment at Section II 3 (b) and Section III. 6(b) (Ex. 15); Herold Aff. at ¶ 14 (Ex. 1).[10]

This ended the State's WAC/AWP lawsuit against GSK. For the reasons explained in Section II. C below, the New York Counties cannot assert any WAC/AWP claims relating to the drugs that were explicitly subject to the 2006 release and dismissal with prejudice in the State of New York Case. The Counties are not barred by the prior release, however, from asserting claims relating to GSK's other drugs, although the New York Attorney General determined in 2006 that no further WAC/AWP litigation by the State was warranted against GSK and dismissed its claims concerning such "other drugs" -- because the State's "other drugs" dismissal was without prejudice. For the reasons explained in Section II. B. below, however, summary judgment in favor of GSK should be granted on the Counties' claims here for the vast majority of these "other drugs" -- because the WACs that GSK reported for them satisfy this Court's previously-articulated WAC List Price test.

C. The Claims Against GSK in the New York Counties' Revised First Amended Consolidated Complaint

Although the WAC/AWP claims of the New York Counties in this lawsuit have been pled, dismissed and repled several times, those that remain against GSK are substantively the same as the claims previously asserted against GSK by the State of New

[10] The State of New York settlement agreement also provided, among other things, that GSK would report certain certified pricing information (including AMPs) directly to the State of New York's Medicaid Program for *all drugs* covered by Medicaid, including those subject only to dismissal without prejudice in that case. GSK's SOF at ¶ 12; Consent Order and Judgment at Section III. 2 and Addendum A (Ex. 15).

York.[11] The Counties allege, with respect to WAC reporters like GSK, that the reported WACs (or WAC equivalents) for Medicaid-covered drugs were "false and inflated," and that "drug manufacturers know that by reporting a false and inflated WAC or WAC equivalent they can trigger the publication of a false and inflated AWP on which reimbursements are made." GSK's SOF at ¶ 13; Revised First Amended Consolidated Complaint ("hereinafter RFACC") at ¶ 12. The New York Counties allege, through Exhibits A and B-18 of the RFACC, that the reported WACs for 270 GSK NDCs (as well as the published AWPs that were allegedly "caused" by these WACs) were false and inflated. GSK's SOF at ¶ 14.[12] On the basis of these allegations, the New York Counties assert that GSK violated New York's Deceptive Acts and Practices statute (N.Y. General Business Law § 349) (Count VI) and the New York statute prohibiting false statements to obtain public funds, N.Y. Social Services Law § 145-b (Count III) -- both of which were asserted in the New York State case. They also assert a common law fraud claim (Count VII). GSK's SOF ¶ 15.[13]

D. There Has Been Extensive Discovery In This Case With Respect to GSK's Medicaid-Covered Drugs.

Although this Court stayed discovery with respect to drugs alleged by the Counties to have "spreads" between acquisition cost and published AWP of 30% or less,

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[11] The New York Counties have also asserted "Best Price/Medicaid Rebate" claims against GSK, most of which were dismissed for failure to comply with Rule 9(b). Those claims are not the subject of this Motion for Partial Summary Judgment.

[12] The RFACC exhibit that lists the GSK drugs at issue (Exhibit B-18) lists two GSK NDCs -- one for Amoxil 500mg capsules (NDC 00029600732) and one for Zofran 2mg/ml vials (NDC 00173044200) -- that were subject to the New York State settlement agreement's explicit release. *See* Section II. C. below. It also lists six NDCs for Ceftin which are not GSK NDCs; those NDCs were for a time-period during which GSK did not distribute or report prices for Ceftin. The two settled NDCs and six Ceftin NDCs distributed by a non-GSK entity were not analyzed under the WAC List Price test discussed herein. GSK's SOF ¶ 14, n.3; *See* Affidavit of Dr. Eric M. Gaier at ¶4, fn. 1 (Ex. 2).

[13] The Counties also asserted other WAC/AWP claims, but they were dismissed by this Court's Memorandum and Order dated April 2, 2007 and were included in the RFACC only for appellate purposes.

GSK has nevertheless produced voluminous data and documents to the New York Counties with respect to virtually all of its Medicaid-covered drugs. On April 18, 2007, GSK entered into a Stipulation with the New York Counties under which it agreed to make the same "GSK Core Documents" and data available to the New York Counties as it produced in multiple other AWP cases around the country, and under which the parties also agreed that GSK's key Rule 30(b)(6) depositions would be cross-noticed in this case. GSK's SOF at ¶ 16; *see* Stipulation (Ex. 4) and Herold Aff. at ¶ 3 (Ex. 1). Pursuant to that Stipulation, GSK has produced detailed sales transaction data for its Medicaid-covered drugs to the New York Counties, as well as a massive quantity of documents (including documents produced in the MDL class action, depositions taken in that case, and multiple productions of documents produced in other state AWP cases). GSK's SOF at ¶ 17; *see* two GSK discovery letters to Joanne Cicala dated April 18, 2007 (Ex. 16); *see also* GSK discovery letters to Joanne Cicala dated, June 13, 2007, February 28, 2008 and June 30, 2008 (collectively Ex. 17) and Herold Aff. at ¶¶ 15-16 (Ex. 1). Between the voluminous discovery that GSK has produced to date and the data and documents otherwise available to the New York Counties (*e.g.*, prices published by the commercial price reporting services, wholesaler data and Medicaid claims data), the New York Counties have long had the data and documents necessary to evaluate their claims under applicable legal standards for all of the GSK drugs they are seeking to place at issue in this case. GSK's SOF at ¶ 18.

E. The Vast Majority of GSK's Sales to Its Customers Were Within 5% of GSK's Reported WAC List Price.

Dr. Eric M. Gaier, a Ph.D. economist who has previously testified before this Court as an expert in the AWP cases, has analyzed GSK's sales transaction data for 262 GSK NDCs at issue in this case (*see* note 12 *supra*) to determine what percentage of sales

for each NDC were made by GSK at or about GSK's reported WAC list prices. The results of Dr. Gaier's analysis are presented, in detail, in the Affidavit of Dr. Eric M. Gaier ("hereinafter Gaier Aff.") and in exhibits accompanying his affidavit, collectively appended to GSK's SOF as Exhibit 2. GSK's SOF at ¶19.

To determine what percentage of GSK's sales were "at or about" GSK's WAC list prices, Dr. Gaier conservatively applied the guidelines set forth in this Court's decision concerning whether WAC list prices were deceptive. *See In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 104-06 (D. Mass. 2007). GSK's SOF at ¶ 20. He analyzed GSK's transaction-by-transaction sales, rebate and chargeback data for all of the NDCs at issue for the period 1997-2005, on an NDC-by-NDC, year-by-year basis. His universe included every GSK commercial U.S. sale to *every class of trade* (*i.e.,* every transaction other than those involving charities, samples or returns). GSK SOF at ¶ 21; Gaier Aff. at ¶¶ 6-7 (Ex. 2). In addition, in order to be conservative in determining the GSK customers' transaction prices net of all discounts, rebates and chargebacks, Dr. Gaier (a) reduced each sale transaction price by 2% based on an assumption that a 2% prompt-pay discount was paid for *all* of GSK's direct sales to wholesalers or providers, and (b) calculated transaction prices by taking into account *all* discounts and rebates given to customers and *all* chargebacks credited as the result of contracts with customers. GSK's SOF at ¶ 22; Gaier Aff. at ¶¶ 6-7 (Ex. 2).

Dr. Gaier followed this Court's decision and concluded that a transaction price was "at or about" WAC only if it was within 5% of the applicable WAC list price. GSK's SOF at ¶ 23; Gaier Aff. at ¶¶ 6-7 (Ex. 2); *see* 491 F. Supp. at 106-08. For each NDC, he determined the percentage of the total number of units sold each year that had a transaction price within 5% of the WAC list price. For purposes of this motion, the NDC

was deemed to have "passed" the WAC List Price test if (after appropriate weighting) more than 50% of the total number of units sold had a transaction price within 5% of the reported WAC. GSK's SOF at ¶ 23; Gaier Aff. at ¶¶ 6-7 (Ex. 2).

The overall results of Dr. Gaier's "WAC List Price" analysis for the GSK drugs at issue in this case are summarized in Attachment B to his Affidavit (Ex. 2).[14] GSK SOF at ¶ 24. For 208 of the GSK NDCs at issue here -- listed in Table B.1 -- the percentage of sales with transaction prices within 5% of WAC is over the 50% threshold for the relevant period, and for the vast majority of these NDCs the percentage is higher than 80% or even 90%. GSK's SOF at ¶ 25; Gaier Aff. at Table B.1 (Ex. 2).[15]

To further demonstrate the impact that the WAC List Price test has on plaintiffs' claims in this case, Dr. Gaier also compared the alleged New York Medicaid reimbursement amounts associated with the GSK drugs that pass the WAC List Price test to the total alleged reimbursements for all of the GSK drugs at issue here. GSK SOF at ¶ 26; Gaier Aff. at ¶ 7 (Ex. 2). Of the approximately $2.143 billion that the New York Counties allege was reimbursed in total for the 262 GSK NDCs analyzed by Dr. Gaier here (a total which includes the New York county, state and federal shares), Dr. Gaier determined that 98.3% ($2.107 billion) of these alleged expenditures relate to the 208

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[14] The detailed year-by-year, NDC-by-NDC breakdown that went into the "WAC List Price" analysis summarized in Attachment B of the Gaier Affidavit is set forth in Attachment D to his Affidavit (Ex. 2). Table D.1 provides the detailed back-up that went into the summary in Table B.1 for the 208 NDCs for which GSK now moves for summary judgment. GSK SOF at ¶ 24; Gaier Aff. Table D.1 (Ex. 2).

[15] Table B.2 of Dr. Gaier's Affidavit (Ex. 2) presents the remaining GSK drugs for which *less than* 50% of the sales -- when assessed *either* by units sold or dollars sold -- were at transaction prices within 5% of WAC. GSK is not moving for summary judgment on these NDCs at this time. All of them are relatively small-volume products -- most had alleged total New York Medicaid reimbursements over the nine-year period at issue of less than $100,000.

GSK NDCs where more than 50% of the sales for the relevant period were made at transaction prices within 5% of the reported WAC list price. *Id.*[16]

II. Argument

A. Summary Judgment Standards

Rule 56(b) provides that a defendant "may move at any time… for summary judgment on all or part of a claim." "Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36 (1st Cir.1995) (quoting Fed.R.Civ.P. 56(c)).

"Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who 'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.'" *Barbour*, 63 F.3d at 37 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S.

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[16] In addition, although GSK is not presently moving for summary judgment on the basis of the AWP "spreads" of its drugs, Dr. Gaier has examined those spreads and has conservatively determined that for the vast majority of the GSK NDCs in this case the spreads are less than 30%. Just as was done for other manufacturers in the Track One MDL trial, Dr. Gaier examined GSK's spreads on an NDC-by-NDC, year-by-year basis and calculated the "spread" percentages as a mark-up from the acquisition cost (instead of as a discount from the AWP). GSK's SOF at ¶ 27; Gaier Aff. at ¶ 8 (Ex. 2). As set forth in Dr. Gaier's affidavit, he was instructed to apply a number of conservative assumptions for purposes of this exercise, so as to avoid potential factual disputes. The overall results of Dr. Gaier's AWP "spread" analysis for the GSK NDCs at issue in this case are summarized in Attachment C to his affidavit (Ex. 2). For all of the NDCs in Table C.1 -- which account for more than 99% of the New York Counties' alleged expenditures for the GSK drugs in this case -- the "spread" is less than or equal to 30% for the relevant period. GSK's SOF at ¶ 27; *See* Gaier Aff. at ¶¶ 8-9 and Table C.1 (Ex. 2). In Attachment E to Dr. Gaier's affidavit, he sets forth the NDC-by-NDC, year-by-year AWP "spread" analysis which formed the basis for the overall results set forth in the summary contained in Attachment C. GSK's SOF at ¶ 27; *See* Gaier Aff. at Attachment E (Ex. 2).

With respect to the GSK NDCs for which GSK *is* moving for summary judgment now (*i.e.*, those which pass the WAC List Price test for the relevant period) all but four (out of 208) of them *also* have AWP "spreads" for plaintiffs' alleged Medicaid classes of trade that are less than or equal to 30%. Dr. Gaier has placed an asterisk in the column on Table B.1 entitled "Percentage of sales units 'at or about' WAC" to indicate that that particular NDC *also* has an AWP "spread" for the relevant period of 30% or less. GSK's SOF at ¶ 28; *See* Gaier Aff at ¶ 10 and Table B.1 (Ex. 2); *see also* asterisks on year-by-year analysis presented in Gaier Aff. Table D.1 (Ex. 2).

242, 256 (1986)). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Barbour*, 63 F.3d at 36. However, "[t]here must be sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir.1990) (quoting *Anderson*, 477 U.S. at 249-50) (quotation marks omitted).

B. Summary Judgment Should Be Entered in Favor of GSK Concerning All NDCs Listed in Table B.1 to the Gaier Affidavit Because These NDCs Pass This Court's "WAC List Price" Test.

1. *This Court's WAC List Price Test*

During the Track One trial in the MDL, defendant BMS argued that its WAC list price (which it called "WLP") was a legitimate list price to wholesalers for all of its drugs. *See In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 104-06 (D. Mass. 2007) (hereinafter "*Track One Opinion*"). BMS asserted that its WAC list prices were not "unfair or deceptive" under the applicable Massachusetts statute, even though they did not reflect discounts or other price concessions and even though some of BMS's products were almost always sold at substantially below the reported WAC. *Id.* at 104-05.

The Court, in considering this argument, turned to the FTC's Guides Against Deceptive Pricing, which are published in the Code of Federal Regulations at 16 C.F.R. § 233.3. As the Court noted, the FTC Guides provide that a list price "will not be deemed fictitious if it is the price at which substantial (that is, not isolated or insignificant) sales are made." *Id.* at § 233.3(d); *Track One Opinion*, 491 F. Supp. 2d at 105. The FTC Guides further provide that, "conversely, if the list price is significantly in

excess of the highest price at which substantial sales in the trade area are made," then they pose a serious danger of being misleading. 16 C.F.R. § 233.3(d). Based on these FTC Guides, the Court held, *as a matter of law*,[17] that "if more than 50 percent of all sales were made at or about the list price, the list price will not be deemed fictitious." *Track One Opinion*, 491 F. Supp. 2d at 105. In applying this test, which we refer to herein as the "WAC List Price" test, the Court considered a sale to be "at or about" the list price if the transaction price (after deducting discounts, rebates and chargebacks) to the manufacturer's direct customers (usually wholesalers) was within 5% of the list price. *Id.* at 106-08.

When the Court applied its WAC List Price test to the BMS drugs at issue in the MDL Track One trial, it examined whether more than 50% of BMS's sales of a particular drug each year were within 5% of WAC. *Id.* The Court consistently held that there was no liability for a particular year when the wholesale list price for that year "passed" the WAC List Price test, even when those prices did not pass the test for other years and even when the AWP "spreads" were greater than the 30% threshold that was applied in that case. *Id.* *See* holdings re Etopophos (no liability because the WAC List Price test was passed even though there was an AWP spread higher than 30% for one year); Paraplatin (no liability because the WAC List Price test was passed, even though the AWP spreads were as high as 67% in one year); Vepesid (no liability for one year out of five, *i.e.*, the year 2000, even though AWP spreads exceeded 30%, because for that year more than 55% of sales were within 5% of WAC); Rubex (even though AWP spreads were above

[17] That is, the test was not based on expert or other evidence concerning industry or payor "expectations," on circumstances even arguably relating to any payor-type, or on fact-specific commercial circumstances. GSK agrees with the MDL Track One trial defendants that there are certainly circumstances under which a list price is not deceptive even when the "WAC List Price" test is not met and when few, if any, sales are close to the list price. For purposes of this partial summary judgment motion, however, the Court need not revisit whether or not it agrees with this position; this motion merely seeks the application of the WAC List Price test that the Court has already articulated.

30% in 2001, no liability for that year because 62% of sales were within 5% of WLP, so the WLP for that year was a "true list price"). Thus, without exception, if a BMS drug passed the WAC List Price test, the Court found no liability.

2. *The Court Should Apply Its WAC List Price Test In This Case.*

Section 349(a) of the New York General Business Law makes unlawful "[d]eceptive acts or practices in the conduct of any business trade or commerce or in the furnishing of any service . . .." This statute is materially identical to the Massachusetts statute at issue in the Track One trial in that both prohibit "deceptive acts or practices." *See* Massachusetts Gen. Laws Ch. 93A, § 2, (prohibiting "unfair or deceptive acts or practices in the conduct of any trade or commerce"). Thus, this Court's holding that list prices complying with the WAC List Price test are not deceptive under the Massachusetts statute should be applied to the claims of the New York Counties under § 349(a).[18]

[18] In fact, the New York Deceptive Acts and Practices statute provides that it is a "complete defense" if "the act or practice is … subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States as such rules, regulations or statutes are interpreted by the federal trade commission or such department, division, commission or agency or the federal courts." N.Y. General Business Law § 349(d). This provision has been construed by New York courts to mean exactly what it says -- there can be no liability for a General Business Law § 349 claim if the challenged conduct is in compliance with the rules and regulations of a federal agency such as the FTC, as interpreted by the courts. *See Porr v. Nynex Corp.*, 660 N.Y.S. 2d 440, 448 (N.Y. S. Ct., App. Div. 1997); *Marcus v. AT & T Corp.*, 938 F. Supp. 1158, 1173 (S.D. N.Y. 1996). The FTC guidelines concerning list prices set forth at 16 C.F.R. § 233.3(d) have already been "interpreted by .. a federal court" -- this Court -- to insulate a WAC list price reporter from liability if more than 50% of the sales for a drug were made at transaction prices within 5% of the reported WAC. If those guidelines are deemed to be the kind of "rules and regulations" covered by § 349(d), then compliance with them as interpreted by this Court is a "complete defense" to the Counties' § 349 claim. On the other hand, even if the FTC Guides are deemed to be mere "guidelines" that do not qualify as "rules and regulations" under § 349(d), compliance with this Court's WAC List Price test should still insulate a defendant from liability under the New York statute just as this Court held to be the case under the Massachusetts statute (which has no comparable "complete defense" language).

3. *Application of This Court's WAC List Price Test Requires Dismissal of All Claims With Respect to the GSK NDCs Listed in Table B.1 to the Gaier Affidavit.*

For the reasons set forth and discussed in Section E of the Statement of Undisputed Facts above, the 208 GSK NDCs listed in Table B.1 to the Affidavit of Dr. Eric M. Gaier all pass this Court's WAC List Price test. Specifically, for all of the NDCs in that table, the percentage of sales during the relevant period with transaction prices that are within 5% of the reported WAC is over 50%. Indeed, for the vast majority of these NDCs, the percentage of sales with transaction prices within 5% of WAC is higher than 80% or even 90%. Of the more than $2 billion that the New York Counties allege was reimbursed (in total) for the GSK drugs they seek to place at issue here, Dr. Gaier determined that more than 98.3% of these alleged expenditures relate to NDCs where more than 50% of the sales during the relevant period were made at transaction prices within 5% of the reported WAC list price. GSK SOF at ¶¶ 24-26; Gaier Aff. at ¶ 7 (Ex. 2).[19]

The bottom line is this: because all of the NDCs listed in Table B.1 to the Gaier Affidavit pass this Court's WAC List Price test, summary judgment should be entered in favor of GSK for all of those NDCs with respect to the Counties' § 349 claim (Count VI).

The failure of the Counties' § 349 claim must also lead to the failure of their two other remaining WAC/AWP claims -- Count VII (for common law fraud) and Count III (for obtaining public funds by false statements). It is well-established under New York

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[19] Because GSK's reported WACs (and WAC-equivalents) for all of the NDCs at issue in this motion clearly pass this Court's WAC List Price test, it is not necessary for the Court also to consider whether to apply its previously articulated AWP "spread" test for these NDCs. *See Track One Opinion,* 491 F. Supp. 2d at 104-08. As noted above, however, Dr. Gaier's analysis *also* shows that almost every one of the GSK NDCs that are subject to this motion for summary judgment *does* pass the AWP 30% "spread" test, or "speed limit" test, previously articulated by this Court in its Track One Opinion. For all but four of the 208 GSK NDCs which pass the WAC List Price test for the relevant period, the AWP "spreads" are 30% or less. GSK SOF at ¶ 28; Gaier Aff. at ¶ 10 (Ex. 2), *see* asterisks for each NDC in Table B.1 to the Gaier Aff. (Ex. 2); *see also* asterisks on Table D.1 to the Gaier Aff. (Ex. 2).

law that a § 349 claim is easier to establish and encompasses broader conduct than a claim sounding in fraud or false statements. *See Gaidon v. Guardian Life Ins. Co. of America,* 94 N.Y. 2d 330, 343, 348 (N.Y. 1999) ("§ 349 contemplates actionable conduct that does not rise to the level of fraud," whereas fraud claims "occupy a civil classification just short of criminal conduct … [and generally require] behavior involving intentional, false representations and other connotations of scienter such as willfulness, knowledge, design and bad faith"); *Gristede's Foods, Inc. v. Unkechauge Nation,* 532 F. Supp. 2d 439, 453 (E.D.N.Y. 2007) (claims asserted under § 349 "are clearly broader than common law fraud"). If the Counties cannot establish their § 349 claim because GSK's reported WACs were not unfair or deceptive as a matter of law, then under no circumstances can they meet their burden of proving their common law fraud or false statements claims.[20]

C. Summary Judgment Should Be Entered in Favor of GSK as to the Counties' Claims Relating to Two GSK NDCs that Were Previously Released as Part of GSK's Settlement Agreement with the State of New York.

The text of the RFACC acknowledges that the GSK NDCs "at issue" in this case include only the "unsettled" NDCs; *i.e.*, those that were not subject to the release in the New York State lawsuit. RFACC at ¶ 485. However, plaintiffs' list of GSK drugs allegedly at issue, set forth in RFACC Exhibit B-18, includes two GSK NDCs -- one for Amoxil 500mg capsules (NDC 00029600732) and one for Zofran 2mg/ml vials (NDC

[20] Moreover, there is simply no support for a fraud or false statements claim here, where (a) there is no dispute that GSK openly and repeatedly defined its reported WACs and WAC equivalents, in its price reporting letters to First DataBank and others, as list prices that did not include discounts, rebates or chargebacks and (b) those WACs and WAC-equivalents satisfy the Court's "WAC List Price" test. In addition, the state court presiding over the New York Attorney General's WAC/AWP case against GSK previously found that the State's claim for obtaining public funds by false statements failed as a matter of law because there was no allegation that GSK obtained public funds. See *People of the State of New York v. Pharmacia, et. al.*, Index No. 905-04, slip. op at 10 (N.Y. Sup. Ct. June 1, 2004) (Ex. 18).

00173044200) -- that were subject to the New York State settlement agreement's release. These drugs are covered under the New York settlement agreement as part of the "Medicaid Zofran/Kytril Injectable/Amoxil Claims." Consent Order and Judgment at Section II 3 (a), Section III. 6(a) and (8), and Attachment 2 (Ex. 15).

Section III. 8 of the New York settlement agreement specifically discharges GSK from any New York Medicaid-related damages payments for these particular drugs:

> . . . The payment by GSK of the amount described in Paragraph III.1 above shall fully discharge the GSK Defendants from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the ***Plaintiff of the State of New York or any of its counties or other subdivisions*** for such Medicaid Zofran and Kytril Injectible/Amoxil Claims.

Id., ¶ III.8 (Ex. 15) (emphasis added). Those claims were also explicitly dismissed with prejudice. *Id.* at ¶ III.6(a) (Ex. 15).

The New York Counties' WAC/AWP claims with respect to these drugs are barred from being re-litigated both under the release and by the doctrine of *res judicata. People, ex rel. Spitzer v. Applied Card Sys., Inc.*, __ N.E.2d __, 2008 WL 2519797 (N.Y., Jun. 26, 2008) (settlement agreements resulting in judgment are given *res judicata* effect; it is the "respect for finality [that] has informed [the] longstanding rule that -- absent exceptional circumstances such as duress, illegality, fraud, or mutual mistake -- a settlement must be enforced according to its terms.") *See also O'Brien v. City of Syracuse,* 54 N.Y.2d 353, 357 (N.Y. 1981). For these reasons, summary judgment should be entered in GSK's favor with respect to the New York Counties' claims concerning Amoxil 500mg capsules (NDC 00029600732) and Zofran 2mg/ml vials (NDC 00173044200).

Conclusion

For all of the reasons set forth herein, this Court should grant GSK's motion for partial summary judgment and enter an Order that grants judgment in GSK's favor with respect to all of the New York Counties' WAC/AWP claims concerning (a) all of the NDCs set forth in Table B.1 of Dr Gaier's affidavit, which satisfy the Court's WAC List Price test, and (b) the two previously-settled GSK NDCs for Amoxil and Zofran.

Dated: November 24, 2008

Respectfully submitted,

Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK")

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CERTIFICATE OF SERVICE

I hereby certify that today I have caused an electronic copy of the foregoing SmithKline Beecham Corporation, d/b/a GlaxoSmithKline's ("GSK's) Memorandum of Law in Support of Its Motion for Partial Summary Judgment in the New York County Cases to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: November 24, 2008

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